

EFFICACY AND SCIENCE SUPPORT BRANCH

EFFICACY REVIEW - I

ANTIMICROBIAL DIVISION

IN 06/16/98 OUT 08/21/98

Srinivas Gowda

Reviewed by Srinivas Gowda Date 08/21/98

EPA Reg. No. or File Symbol 69268-R (8% A.I. H₂O₂)

LAN Code

EPA Petition or EUP No. None

Date Division Received 05-20-98

Type Product Non-Food Contact Surface Sanitizer

MRID No (s) 445320-02, 445320-03, and 445601-01

Product Manager PM 31 (MSwindell)

PM Team Reviewer Tony Kish

Product Name H₂ORANGE₂ SUPER CONCENTRATE 112

Company Name ALPHEN, INC.

Submission Purpose New Application

Type Formulation Liquid

Active Ingredient (s): %

Hydrogen peroxide.....7.95

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202.0 Recommendations

202.1 Efficacy Supported by the Data:

The submitted data by the Modified EPA's Sanitizer Test Method appear adequate to support effectiveness of the product as a non-food contact surface sanitizer against Salmonella choleraesuis ATCC 10708, Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Klebsiella pneumoniae ATCC 4352, Escherichia coli ATCC 25922, and Streptococcus faecalis 19433 and when used at a concentration of 1450 ppm hydrogen peroxide on precleaned, hard, non-porous surfaces for a contact time of 5 minutes at room temperature. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

Also, the submitted data by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against HIV-1(AIDS virus) when tested at 2.710 g. concentrate + 997.3 g of 415.6 ppm synthetic hard water and 2.778 g. concentrate + 997.2 g of 415.6 ppm synthetic hard water dilutions on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 5 minutes at 21°C. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

Also, the submitted data by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Herpes simplex virus Type II ATCC VR-734 and Influenza A₂ /Japan/305/57, ATCC VR-100 when tested at a concentration of 500 ppm hydrogen peroxide (13.889 ml. product + 986.111 ml. sterile deionized water) on precleaned, hard, non-porous surfaces for a contact time of 5 minutes at 20°C. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

202.2 Additional Data/Information Required to Support Efficacy:

- a. Submit raw data of all three studies.
- b. Submit characterization data (identity, strength, purity, and composition of test substances, lot numbers 97199, 97220, 97227, 168, 181, 97168, 97181, 10003, 10004, 10053, and 10054) to verify if the efficacy data were developed at the proper concentrations.

203.0 Labeling:

The proposed product name "H₂ORANGE₂ SUPER CONCENTRATE 112" is not acceptable. Propose another name.

On the Front Panel:

a. delete "...1-STEP CLEANER..." because the sanitizing data were not developed in the presence of 5% blood serum to support one-step sanitizing claim.

b. "Virucide" claim must be keyed by a symbol to the paragraph listing the tested viruses. Therefore, change "...VIRUCIDE..." to "...VIRUCIDE*...".

c. Change "...HARD SURFACES..." to read "...HARD NON-POROUS SURFACES..."

On the Right Panel change "1-Step Cleaning and Sanitizing:" to read "For Cleaning and Sanitizing:", and change "...thoroughly clean the surface, allow to air dry" to read "...thoroughly clean the surface, then apply same solution to the surface to sanitize, allow to remain wet for 5 minutes and air dry."

On the Back Panel change "...kills 99.99..." to read "...kills 99.9%..."

On the Back Panel change "...Herpes 2..." to read "...Herpes simplex Type 2..."